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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/786,043	08/13/2001	Ismail Kola	DAVI121.001A	6828

20995 7590 05/05/2004

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EXAMINER	
ANGELL, JON E	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 05/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/786,043	KOLA ET AL.	
	Examiner	Art Unit	
	J. Eric Angell	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *110-113* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *110-112* is/are rejected.

7)☒ Claim(s) *113* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 February 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/22/04 has been entered.

2. Claims 1-109 and 114-158 have been cancelled. Claims 110-113 have been amended. Claims 110-113 are currently pending in the application and are examined herein.

3. Applicant's arguments with respect to the rejection of claims as they pertain to the amended claims are addressed on a per section basis. The text of those sections of Title 35, U.S. Code not included in this Action can be found in a prior Office Action. Any rejections not reiterated in this action have been withdrawn as being obviated by the amendment of the claims and/or applicant's arguments.

Claim Objections

4. Claim 110 is objected to because of the following informalities: The claim does not appear to be as clear as possible. Specifically the underlined part of the phrase "An isolated nucleic acid molecule comprising a nucleotide sequence encoding, or a nucleotide sequence complementary to a nucleotide sequence encoding, an amino acid sequence..." is not perfectly clear. It is recommended that the claim be amended into two different claims, one claims being drawn to a nucleotide sequence encoding SEQ ID NO. 2, and another claim drawn to a

nucleotide sequence complimentary to a nucleotide sequence encoding SEQ ID NO. 2. Such an amendment would make the claims perfectly clear and obviate this objection.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 110-112 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims encompass an isolated nucleic acid molecule comprising a nucleotide sequence encoding an amino acid sequence as set forth in SEQ ID NO. 2, or having at least 45% similarity to SEQ ID NO. 2, wherein said amino acid sequence comprises an ETS domain, as well as a nucleotide sequence complementary to the encoding nucleotide sequence (claims 110 and 112) as well as an isolated nucleic acid molecule comprising **a** nucleotide sequence as set forth in SEQ ID NO. 1, or which hybridizes to SEQ ID NO. 1 under medium stringency conditions (claim 111).

Therefore, the claims are very broad and encompass nucleotide sequences that encode amino acid sequences that are at least 45% similar to SEQ ID NO.2 wherein the amino acid sequence comprises an ETS domain, as well as **any** nucleic acid sequence as set forth in SEQ ID

NO. 1, including fragments, variants and allelic variants thereof. However, the specification has not adequately described the genus of molecules encompassed by the claims.

With respect to the claims that encompass nucleic acids encoding variants of S ID NO. 2, the genus of molecules encompassed by these claims encompass all nucleotide sequences that encode a polypeptide that is at least 45% similar to SEQ ID NO. 2 and comprises an ETS domain. This genus of molecules is very large and encompasses molecules which do not have the same function as the amino acid sequence set forth in SEQ ID NO. 2.

With respect to the claims drawn to variants of SEQ ID NO.1, the genus of molecules encompassed by these claims is encompass any isolated nucleic acid molecule comprising **a** nucleotide sequence as set forth in SEQ ID NO. 1 (i.e., any sequence of SEQ ID NO. 1), or which hybridizes to SEQ ID NO. 1 under medium stringency. This genus of molecules is very large and encompasses molecules which do not have the same function as the sequence set forth in SEQ ID NO. 1.

The Written Description Guidelines for examination of patent applications indicates, "the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, or by disclosure of relevant, identifying characteristics, i.e. structure or other physical and/or other chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show applicant was in possession of the claimed genus." (See MPEP 2100-164).

As indicated above, the claim encompass a large number of amino acid sequences, including all amino acid sequences that are 45% similar to SEQ ID NO.2 and which comprise an

ETS domain. As indicated in the specification, as well as the prior art, an ETS domain is a domain that interacts with a specific DNA sequence such that the amino acid sequence binds to the DNA sequence. The amino acid sequence that is SEQ ID NO. 2 has been shown, by example, to bind to a specific DNA sequence domain via the ETS domain, which then results in the increase in the transcription of the associated mRNA. Although, based on the disclosure of the specification and the teachings in the prior art, one of skill in the art would readily recognize a polypeptide comprising an ETS domain, there is insufficient disclosure such that one skilled in the art would be able to recognize which amino acid sequences encompassed by the claims would have transcriptional activity and which ones would not, without performing further experimentation. There does not appear to be a disclosure indicating the common critical elements of amino acid sequences encompassed by the claims other than the ETS domain. For instance, there is no disclosure indicating structural elements that are critical for the transcriptional function of the amino acid sequence. Without identification of the critical elements of the amino acid sequences encompassed by the claims, it would be impossible for one of skill in the art to determine which amino acids sequences 45% similar to SEQ ID NO. 2 and comprising an ETS domain would be functional transcription factors and which ones would not be functional transcription factors without performing additional experimentation. As such, the specification has not adequately described the genus of molecules encompassed by the claims. It is noted that claim 112, depends on claim 111, therefore claim 111 must, by definition, encompass all limitations of claim 112. Therefore, although claim 111 does not specifically indicate that the nucleic acid sequence encodes an amino acid sequence that is at least 45%

similar to SEQ ID NO. 2 with an ETS domain, since dependent claim 112 sets forth this limitation, claim 111 must also encompass this limitation.

With respect to the genus of SEQ ID NO. 1 variants, the specification has not disclosed any critical elements of SEQ ID NO. 1 which confer the desired function to the sequence. That is, the specification has not disclosed which variants of SEQ ID NO. 1 would encode a polypeptide that function as an ETS transcription factor. Without a clear indication of the critical elements required for the proper function of SEQ ID NO. 1, additional experimentation would be required in order to identify those structural elements which are critical to the function of all SEQ ID NO. 1 variants encompassed by the claims.

7. Claims 110-112 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, in view of the written description rejection above. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

8. As mentioned above, the claims encompass amino acid sequences for which there is insufficient written description provided in the specification. Furthermore, the claims encompass molecules, which, although they may have some sequence similarity to SEQ ID NO. 1 and 2, do not necessarily have the same function. For instance, the claims are drawn to a nucleotide sequence encoding SEQ ID NO. 2 or an amino acid sequence that is 45% similar to SEQ ID NO. 2 and which comprises and ETS domain. As indicated above, the claim encompasses molecules which are transcription activators (such as SEQ ID NO. 2), as well as molecules which do not activate transcription, and which may inhibit transcription by binding to the ETS domain and

preventing functional molecules from binding to the ETS domain. Without a clear indication of the sequence which are critical for the function of the molecules encompassed by the claims one of skill in the art would not know how to make or use the claimed invention without performing an undue amount of additional experimentation in order to first identify the minimal critical elements common to all members of the genus.

It is noted that amending the claims to be limited to an isolated nucleic acid sequence encoding the sequence set forth in SEQ ID NO. 2 (or an isolated nucleic acid sequence comprising the sequence set forth in SEQ ID NO. 1) would obviate this rejection.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 10-112 are rejected under 35 U.S.C. 102(b) as being anticipated by Buchert (BBRC, 1998; Vol. 246, pp. 176-181, previously cited).

Claim 110 is drawn to an isolated nucleic acid comprising a nucleotide sequence encoding **an** amino acid sequence as set forth in SEQ ID NO. 2 or that has at least 45% similarity to SEQ ID NO. 2 and which also has an ETS domain. It is respectfully pointed out that the claims reads on "**an** amino acid sequence as set forth in SEQ ID NO. 2". As such the claim reads on **any** amino acid sequence set forth in SEQ ID NO. 2, as long as the sequence comprises

an ETS domain. Bochert teaches an isolated nucleic acid that encodes an amino acid sequence that comprises an ETS domain, and which also comprises an amino acid sequence set forth in SEQ ID NO. 2 (see p. 178, Figure 1 and attached sequence alignment of amino acids 237-248).

Claim 111 is drawn to an isolated nucleic acid molecule comprising **a** nucleotide sequence as set forth in SEQ ID No. 1, **or** which hybridizes to SEQ ID NO. 1 under medium stringency conditions. It is respectfully pointed out that the claim encompasses an isolated nucleic acid comprising **any** nucleotide sequence set forth in SEQ ID NO.1, as well as any oligonucleotide which would hybridize to SEQ ID NO. 1 under medium stringent conditions. Bochert teaches **a** nucleic acid sequence as set forth in SEQ ID NO: 1, as well as **a** nucleic acid sequence which would bind to the nucleic acid of SEQ ID NO: 1 under medium stringency conditions. For example, the nucleotide sequence ATG (see Figure 1, page 178), is a nucleotide sequence set forth in SEQ ID NO 1. Furthermore, the nucleotide sequence ATG as well as the nucleotide sequence encoding the ETS domain (see Figure 1, p. 178) would hybridize to SEQ ID NO. 1 under medium stringency conditions, absent evidence to the contrary.

Claim 112 is drawn to the nucleic acid of claim 111 which further encodes a sequence set forth in SEQ ID NO. 2. It is respectfully pointed out that claim 111 encompasses an isolated nucleic acid molecule comprising **a** (i.e., **any**) nucleotide sequence as set forth in SEQ ID No. 1, **or** which hybridizes to SEQ ID NO. 1 under medium stringency conditions. Therefore claim 112 is drawn a nucleotide sequence of claim 111 that additionally comprises any other sequence set forth in SEQ ID NO. 2. The sequence alignment of SEQ ID NO. 2 and the amino acid sequence taught by Bochert is included (see attachment 1) to show that Bochert teaches a

nucleotide sequence set forth in SEQ ID NO.1 and additionally another amino acid sequence of SEQ ID NO. 2. Figures 1 and 2 in Bochert indicate that the sequence comprises an ETS domain.

Therefore, the instant claims are clearly anticipated by Bochert.

It is noted that amending the claims to be limited to an isolated nucleic acid sequence encoding the sequence set forth in SEQ ID NO. 2 (or an isolated nucleic acid sequence comprising the sequence set forth in SEQ ID NO. 1) would obviate this rejection.

Response to Arguments

11. Applicant's arguments filed 3/22/04 have been fully considered but they are not persuasive.

12. With respect to the rejection of claims under 35 USC 112, first paragraph for insufficient written description, applicants' argue that those of ordinary skill in the art can determine, without undue experimentation, whether a particular sequence falls within the scope of claims. Applicants also argue that the steps used to determine whether any given polypeptide exhibits the same functional activity of the claimed sequence is a matter of routine experimentation (see p. 10 of the response). Applicants indicate that gel shift assays as well as transcription assays are well known methods to determine the function of a polypeptide.

13. In response, it is respectfully pointed out that the claims are first rejected under 35 USC 112, first paragraph because the specification does not sufficiently describe the genus of molecules encompassed by the claims. It was pointed out previously, and reiterated above, that additional experimentation would be required in order to identify which molecules encompassed by the claims would be functional sequences and which not be functional. Since additional

experimentation is required to identify the functional sequences encompassed by the claims it is clear that the written description requirement has not been met. As indicated above, there must be a sufficient disclosure such that the critical structure-function relationship has been identified. That is, the minimal critical elements required for function of the sequences must be identified. Here, applicants have identified only the ETS domain, which is critical for the sequence to bind to DNA. However, the other critical elements which are required for the transcriptional activation activity of the sequences have not been identified. Furthermore, applicants' arguments that additional experimentation would be routine to identify which sequences encompassed by the claims are function is not persuasive because applicants' arguments clearly indicate that additional experimentation is required to identify the functional sequences encompassed by the claims. In order to meet the written description requirement, the description provided must not require additional experimentation in order to determine which sequences would be functional. With respect to the enablement rejection, it is respectfully pointed out that the enablement rejection is in view of the written description rejection. As such, since the specification has not adequately described the molecules encompassed by the claims, one of skill in the art would not know how to make/use the claimed invention without performing additional experimentation. Since the experimentation would first have to determine the minimal critical elements that are required for the function of the sequences encompassed by the claims, the amount of additional experimentation required is considered to be undue. This is because it would not be a matter of determining if a particular sequence encompassed by the claims is functional or not—a matter which would only require routine experimentation. Rather, the additional experimentation required is not routine because the experimentation would require determining the critical

structural elements common to the sequences encompassed by the claims wherein the critical structural elements are critical for function of the sequence. Therefore, the amount of additional experimentation required to make and use the claimed invention would require an undue amount of additional experimentation.

Claim Objections

14. Claim 113 is objected to as being dependent upon a rejected base claim (claim 110), but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. That is, if claim 113 were re-written as: An isolated nucleic acid molecule comprising the sequence set forth in SEQ ID NO. 1, the claim would be allowable.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Eric Angell whose telephone number is (571) 272-0756. The examiner can normally be reached on M-F (8:00-5:30) with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on (571) 272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DAVE T. NGUYEN
PRIMARY EXAMINER

Jon Eric Angell, Ph.D.
Art Unit 1635

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DR   InterPro; IPR003118; SAM_PNT.
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RT   "Molecular cloning and expression of Ehf, a new member of the ets
RT   transcription factor/oncoprotein gene family.";
RL   Biochem. Biophys. Res. Commun. 246:176-181(1998).
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Attachment to Office Action Page 1 of 1

Accession: AF035527